DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR - 5 2002

ANADA 200-318

Susan L. Longhofer, DVM., MS., DACVIM
Vice President, Research & Development
Virbac North America
3200 Meacham Blvd.
Fort Worth, TX 76137

Dear Dr. Longhofer:

We refer to your submission dated December 27, 2001, for Virbamec (ivermectin) Pour-On for Cattle, ANADA 200-318. The submission provides your new distributor labeling for [ ]. You state that [ ] will distribute and market your product under the tradename "[ ]", and that the revised labeling will specify the distributor's name and address.

We note that the labeling does not include the qualifying phrase "Manufactured for" or "Distributed by" as required under 21 CFR 201.1(h)(5), nor does it provide the name and address of the distributor. Because the labeling fails to include this required language, the marketing of your product by [ ] under the submitted labeling would cause your product to be misbranded under section 502(a) of the Federal Food, Drug, and Cosmetic Act. See 21 CFR 201.1(l).

We request that you have your distributor [ ] labeling revised to include the required information. Pursuant to 21 CFR 514.8 (a)(6)(iii), submit this information with a Distributor Statement as soon as possible, or in any event within 30 days of the date of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

[ ]

Mohammad I. Sharar, DVM., M.Sc.
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and Regulatory Review Team II, HFV-216
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